

**REMARKS**

Applicants express appreciation for the interview of July 21, 2010 and the Interview Summary of July 23, 2010. In the Interview Summary, the Examiner indicated that during the interview, Applicants pointed out that new claim 19 contained all of the limitations of original claim 16 and therefore the finality of the rejection is improper. In the Summary, the Examiner further pointed out that she agreed and indicated that the finality of the action of June 15, 2010 would be withdrawn upon the submission of a formal response.

Also, based on the June 2010 Office Action, it is understood that the earlier rejection based on U.S. Patent No. 5,551,419 to Froehlich et al. ("Froehlich") in view of U.S. Patent No. 5,704,345 to Berthon Jones ("Berthon-Jones") has been withdrawn in favor of the present ground of rejection. The Examiner acknowledged at the bottom of page 3 of the final rejection that applicants' earlier argument was correct in that Froehlich and Berthon-Jones together do not teach the invention:

Froehlich as modified by Berthon-Jones further lacks setting one pressure parameter to a first treatment pressure in accordance with the first index during expiration and another pressure parameter to a second treatment pressure based on the second index during inspiration.

Other arguments made in the May 2010 Amendment relative to the combination of Froehlich and Berthon-Jones remain applicable. In this response, Applicants provide remarks which focus specifically on distinguishing the present

invention from U.S. Publication No. 2002/0088465 to Hill ("Hill") and the sole ground of rejection identified in the June 2010 Office Action.

Claims 19-79 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Froehlich in view of Berthon-Jones and Hill. Independent claims 19, 34, 50, and 65 are being amended to better define that the indices of the claims are distinct from each other and are determined based upon different characteristics of the signals generated by at least one sensor. Claims 20-21, 24-29, 39, 41-42, 49, 51-52, 55-60, 70, and 72-73 are being cancelled.

The claims of the present invention are distinguishable from the references in that they include identifying two distinct indices or events. Each is determined independently from the other and each is based on a different manifestation of sleep disordered breathing. These two determined events/indices are used to set two different pressure treatment levels for treating a patient, each set independently of the other. In some claims, the two manifestations are 1) apnea, hypopnea, or snoring, and 2) flow flattening. The cited references either set one treatment level or set two treatment levels based upon a single-sourced event, and none of the references is directed to independently setting two parameters based on two different manifestations of sleep disordered breathing.

As stated in the Remarks to the Amendment submitted on May 14, 2010, Froehlich does not independently set two different parameters.

While the Froehlich reference does teach bi-level operation and adjustments based on the detection of respiratory events, the two

pressure waveforms (for the two phases of a respiratory cycle) are not changed independently based on the detection of respective types of respiratory events. ... And the secondary reference, Berthon-Jones, also does not teach this feature of separate pressure controls for the two phases based on detection of respective types of respiratory events.

Hill is relied upon specifically for using indices to vary both IPAP and EPAP to counter a single sleep disordered breathing event. (Office Action, page 3, last paragraph). That is, Hill is relied upon particularly for disclosing an index-based two-pressure setting which, as stated by the Examiner in the present Office Action, was not disclosed or suggested by the combination of Berthon-Jones and Froehlich. In the Interview Summary, the Examiner stated:

Hill discloses adjusting IPAP via a number that is determined by a calculation and compared against a threshold (paragraphs 49-51). Examiner felt that this calculated number can be considered an "index." Examiner also noted that Hill clearly discloses an index used for EPAP (paragraph 66) and therefore it appears as though both IPAP and EPAP can be adjusted via the use of several indices. In addition, Examiner argued that Berthon-Jones discloses the use of two indices, but only for the adjustment of IPAP pressure. However, since Hill discloses in paragraph 53 that sometimes it is necessary to also adjust EPAP when IPAP adjustments are not enough to treat a patient, Examiner maintained that the combination of Berthon-Jones and Hill would include at least two indices that control IPAP (from Berthon-Jones's method) and EPAP (from Hill's method).

However, Hill is directed "to determin[ing] whether the patient is experiencing Cheyne-Stokes breathing" and does so by monitoring peak flow (paragraph 0011). Hill does not monitor pressure or any other measure of flow in determining whether the patient is suffering from Cheyne-Stokes breathing. The two indices in Hill identified by the Examiner are referred to in these remarks as "Hill's IPAP index" and

“Hill’s EPAP index” and each is set based on an indication of Cheyne-Stokes respiration (CSR), which is identified based on peak flow. Hill’s IPAP index (discussed in detail in Hill’s paragraphs 0049-0051) is based only on measured peak flow and a target peak flow (see paragraph 0049) and is used to set IPAP. Hill’s EPAP index (discussed in detail in Hill’s paragraphs 0060-0066) is comprised of three identified components (see FIG. 3) – (1) a CSR shape index, which is based on a sequence of peak flows, (2) a CSR severity index, which is calculated from an array of peak flows, and (3) a pressure support index, which is “a measure of amount of assistance that is being provided by the pressure support system in attempt to combat the CSR cycle” (paragraph 0065). The pressure support index is not a measure of a parameter associated with the CSR cycle. (paragraph 0065).

With regard to sensed data, both indices in Hill are based on the same sensed data – peak flow. In Hill, the same determined characteristic is used to indication change both IPAP and EPAP, even though IPAP and EPAP may be changed differently and at differently times. It is clear from reading Hill that there is only one type of sleep disordered breathing that prompts all changes – CSR – and that only one sensed characteristic – peak flow – is used for all adjustment. Hill does not disclose or suggest the present claims, in which two characteristics are determined independently of each other, each of which is used for establishing a different pressure treatment. In the absence of two different types of characteristics (or events) that cause adjustments of different ones of IPAP and EPAP, Hill cannot possibly anticipate the claims in issue.

Specifically with regard to the Berthon-Jones related comment in the Interview Summary, it appears that the Examiner agrees that the indices of Berthon-Jones only relate to IPAP and not EPAP. The present claims are directed to setting two different treatment pressures, not only one as in Berthon-Jones. Further, despite the Examiner's argument that Berthon-Jones in combination with Hill suggests setting both IPAP and EPAP, it is clear that the indices used for setting IPAP and EPAP in the present invention are completely different from any disclosed or suggested in Berthon-Jones in combination with Hill.

For the reasons described above, none of Berthon-Jones, Froehlich, or Hill, either alone or in combination, disclose or suggest the present claims. The early passage to issue of the application is respectfully requested.

Respectfully submitted,  
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